

REMARKS

Claims 1-8, 10-13, 22, 24, and 25 remain pending in this application. No new matter has been added. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 1-5, 7, and 10-13 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Richter (EP Patent No. 0976417A) in view of Cohen (U.S. Patent No. 5,167,239) and Ackerman et al. (U.S. Patent No. 6,802,825). The issue here is whether Ackerman teaches that fluid displacement sleeve 12 moves balloon 21 along catheter 11. The Examiner concedes that neither Richter or Cohen shows an anchoring module that includes a drive mechanism that allows it to be advanced along the guide wire to a desired location. To support the contention that Ackerman teaches the movement of balloon 21, the Examiner states that “[d]isplacing the fluid [inside the balloon] also causes the balloon, or at least a portion of the balloon, to be slid forward as well.” Office Action at page 3 (insertion added). Applicants respectfully submit that no support for this contention exists in Ackerman. The portion of Ackerman that the Examiner relies on, column 5, lines 35-44, reads as follows:

As shown in FIG. 6, the distal and proximal portions 21a, 21b of the balloon 21 are inflated by sliding the fluid displacement sleeve 12 distally along the catheter body 11 so that the sleeve 12 slides over the end of the proximal portion 21b of the balloon 21. As the sleeve slides over the proximal portion 21b of the balloon 21, the fixed volume of fluid (e.g. air or saline) sealingly contained therein is displaced or redistributed to inflate and expand the distal and proximal portions 21a, 21b of the balloon 21, thereby forming a barbell-shape balloon structure which conforms to and thus occludes the exterior and interior OS of the cervical canal and sealingly affixes and stabilizes the catheter apparatus 10 in place therein. If used, the stylet assembly 14 can now be removed from the catheter body 11.

Instead of stating that the sleeve displaces the balloon 21, the passage states merely that the balloon displaces the fluid inside the balloon 21. The “sleeve slides over the

proximal portion 21b of the balloon”; it does not push the proximal portion 21b along catheter 11. Moreover, it is not the case that displacing the fluid inside the balloon 21 means that balloon 21 must be displaced as well. In fact, Ackerman contradicts the Examiner when it states that the “elongated inflatable balloon 21 (shown in the deflated state), about 4 inches in length L_{balloon} , *is sealingly affixed* to and encloses a distal portion of the catheter body 11.” Column 3, lines 24-27. Thus, as the sleeve 12 slides over the proximal end 21b of the balloon 21, the balloon remains fixed at the position where it was sealed to the catheter 11, so that the force applied by the sleeve 12 is transmitted through the balloon surface and applied to the fluid inside. Since the sleeve 12 slides over the balloon 21, it does not move the balloon 21 along the catheter 11. The balloon 21 changes shape as a result of the fluid inside being displaced, but a change in shape in the balloon 21 does not mean that the balloon 21 as a whole moves along the catheter 11. The Examiner also asserts that the surface of the balloon 21 is redistributed along with the fluid inside the balloon 21, as if the balloon surface follows the fluid in response to the movement of the sleeve 12 over the balloon. The Examiner offers no evidence of this, nor is it to be regarded as true that a change in shape of the balloon surface necessarily involves movement along the catheter 11, which is the only motion relevant to the claim, since the claim recites movement *along* a guide wire. At most, the change in shape in balloon 21 is a fluctuation of the balloon surface in a direction perpendicular to the catheter 11. As the fluid is pushed forward, the portion of the balloon 21 that receives the increased volume of fluid expands in a direction perpendicularly away from the catheter 11. Since such expansion occurs perpendicularly to the catheter 11, it means that no motion occurs *along* the length of the catheter 11. Therefore, the change in shape of the balloon 21 in Ackerman is not a motion along catheter 11. Accordingly, the change in shape of balloon 21 is not relevant to the claim limitation “to move the anchoring module along the guide track to the desired location.” In view of this discussion, withdrawal of this rejection is requested.

Claim 8 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Richter in view of Cohen, Ackerman, and Kindlein (U.S. Patent No. 7,229,401) or Ziegler (U.S. Patent No. 6,971,900). Since neither Kindlein nor Ziegler overcomes the deficiencies

noted above with respect to Richter, Cohen, or Kindlein, withdrawal of this rejection is requested.

Claim 6 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Richter in view of Kindlein or Ziegler. Claim 6 recites that the threaded member includes a threaded hole. Neither Kindlein, Ziegler, or Richter teaches this particular limitation; therefore, withdrawal of this rejection is requested. The Examiner does not point to any portion of these references that includes such a limitation. Rather, the Examiner states the belief that one of ordinary skill in the art, despite the absence of this limitation in all the references relied upon, would have somehow arrived at this limitation. Applicants traverse this reasoning and respectfully request that, if the Examiner decides to maintain this rejection, that it be supplemented with evidence that actually shows the particular threaded hole limitation. In the absence of such evidence, Applicants submit that claim 6 is patentable over these references.

Claims 22, 24, and 25 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Richter in view of U.S. Published Patent Appln. No. 2002/0065523 to McAlister et al. and Cohen. According to the Examiner, Cohen teaches an anchoring module that one of ordinary skill in the art would have been able to modify into a movable anchoring module based on the teaching in Richter of a module that can move along a guide wire. Applicants disagree with this argument. There is no reason why one of ordinary skill in the art would modify the anchoring balloon 14 of Cohen by enabling it to move along a guide wire based on the teachings of Richter. At most, the combination of these two references would combine a guide wire anchored by stationary balloon 14, as taught by Cohen, with a motor 1, as taught by Richter, that would crawl along the guide wire. The irrelevance of Richter to anchoring balloon 14 can be understood by considering the purpose of Richter. As stated in column 1, Richter is directed to imparting a self-propelling capacity to devices that had been manually movable by a surgeon. That is, Richter is relevant to devices that are capable of being manually pushed along a guide wire to a particular anatomical location. The idea of Richter is to remove the need to manually move such devices by incorporating in them the ability to move by employing a motor. Thus, Richter applies only to non-motorized, but manually movable, devices. It

has no relevance to devices, such as anchoring balloon 14, that are intended to remain permanently affixed at a particular location on a catheter or guidewire.

In addition, the structural differences between the Ackerman balloon 14 and a rigid structure such as motor 1 of Richter cast doubt on the combination of Cohen and Richter. The Ackerman balloon 14 has many substantial differences over motor 1 that would render it unsuitable for incorporating the motor 1 of Richter. For instance, balloon 14 has a flexible, soft surface that by its nature makes it prone to shredding. That propensity to shred would dissuade one of ordinary skill in the art from incorporating into the balloon 14 a motor since, once inside a body and thus pressed from without by its contact with bodily organs and other anatomical structures, there would be a risk that the material of the balloon would get caught in the gearing of the motor. Even if the motor were to be covered with a casing inside the balloon 14, the casing would still include a longitudinal channel for accepting the guidewire. That channel would present a risk that the material of the balloon would be pushed into it as a result of the balloon material being pressed against some anatomical feature inside the body of the patient. Thus, a problem with the proposed combination is that the references do not enable one of ordinary skill in the art to construct a motorized balloon that would overcome this risk. Accordingly, in view of this discussion, withdrawal of this rejection is requested.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, and an early and favorable action on the merits is earnestly solicited.

Respectfully Submitted,

Dated: May 27, 2009

By: 

Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, N.Y. 10038
(212) 619-6000 (telephone)
(212) 619-0276 (facsimile)